PATENT
Docket No. CHAN-33 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Kwan-Ho Chan	)	
		)	
Serial No.:	10/680,079	)	
		)	Group Art
Filed:	October 7, 2003	)	Unit: 3731
		)	
For:	SURGICAL REPAIR KIT AND ITS METHOD OF USE	)	
		)	
Examiner:	Julian W. Woo	)	

APPELLANTS' APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party in interest in this case is Stryker Endoscopy.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 35 claims. Claims 36-41 were added by amendment. Claims 1-7, 9-16, 18, 22, 24-30, 33-35, and 37 have been previously

canceled. Claims 8, 17, 19-21, 23, 40 and 41 are cancelled in a concurrently filed amendment. Claims 31, 32, 36, 38 and 39 are pending, rejected, and under appeal.

IV. Status of Amendments Filed Subsequent to Final Rejection

Submitted concurrently herewith is an amendment in which claims 8, 17, 19-21, 23, 40 and 41 are cancelled, independent claim 36 is rewritten to incorporate all the subject matter of now cancelled claim 23, and claim 32 is amended to correct a wording error. This amendment is filed in accordance with 37 CFR 41.33(b).

V. Summary of Claimed Subject Matter

Independent claim 36 is directed to a surgical apparatus 600 for delivering and retrieving suture, comprising a cannula 602 having a distal end, a proximal end, and a lumen extending therebetween, and a handle 604 having a distal end, a proximal end 618, a passageway 616 extending through at least a portion of said handle, and an exposed surface 632 disposed between the passageway 616 and the distal end of the handle (Figs. 65-66, paragraphs 234-240). The proximal end of the cannula 602 is attached 608 to the handle 604, and the lumen of the cannula 602 is in communication 612 with the exposed surface 632 of the handle 604 (Fig. 66, paragraphs 237-240). The exposed surface 632 is adapted to support a suture extending through the handle such that the suture is manually engageable by an operator for freely moving the suture selectively in the direction of the handle distal end and in the direction of the handle proximal end (Figs. 68-70, paragraphs 240-241). The passageway 616 is provided with an opening 622 at the handle proximal end 618 wherein the opening is positioned to permit the suture to be fed into the opening along a pathway parallel to the lumen (Figs. 65-66, paragraphs 238-239). At least a

portion 638 of the distal end of the cannula 602 is configured to drive a suture against tissue without severing the suture (Figs. 42 and 43, paragraphs 222 and 228; Fig. 66, paragraph 244).

Independent claim 38 is directed to a surgical apparatus for delivering and retrieving suture, the apparatus comprising a passer assembly 600 and a puller assembly 700, 708 (Figs. 73-77, paragraphs 252-254). The passer assembly 600 comprises a handle 604 and a cannula 602, said handle 604 comprising an elongated body having (i) a passageway extending distally from a suture entryway 612 at a proximal end portion of said body (Figs 65-66, paragraph 237), (ii) a recess 630 in said body defining a planar surface 632 generally extending along an axis of the passageway and disposed proximate a distal end of said body, and (iii) a nose portion 608 extending distally of said recess and defining a bore in communication 612 with the passageway and the planar surface 632 (Figs. 65-66, paragraphs 237-240). The cannula comprises an elongated tubular member 602 defining a lumen, a proximal end of said cannula 602 being adjacent to and in communication with said nose portion 608 of said body, the lumen being in alignment with the bore of the nose portion 608. (Figs. 65-66, paragraphs 237-240). The puller assembly comprises a suture engager 700, 708 movable through the nose portion 608 bore and through the cannula lumen, distally to connect to a suture and proximally to withdraw said suture engager and the connected suture (Figs. 75, 79, paragraphs 253-255).

Claim 39 is directed to the apparatus of claim 38, wherein the planar surface 632 is adapted to support a selected one of a suture extending through said handle 604 and said puller assembly shaft 704, 712 extending through said handle, such that the suture

and said puller assembly shaft are each manually engageable by an operator for moving the suture and said puller assembly shaft selectively in the direction of the nose portion 608 and the cannula 602, and in the direction of the body proximal end portion for rearward movement of the puller assembly 700, 708 and suture out the axially disposed passageway at the proximal end of the body (Figs. 74-75, 78-79, paragraphs 253, 255).

Claim 31 is directed to the apparatus of claim 39, wherein the puller assembly is a loop retriever 700, the planar surface 632 permitting the loop retriever shaft 704 to be articulated between a retracted position wherein said loop retriever is retained in said cannula, and an advanced position wherein said loop retriever is connectable to the suture (Figs. 74-75, paragraph 253).

Claim 32 is directed to the apparatus of claim 39, wherein the puller assembly is a hook retriever 708, the planar surface 632 permitting the hook retriever shaft 712 to be articulated between a retracted position wherein said hook retriever is retained in said cannula, and an advanced position wherein said hook retriever is connectable to the suture (Figs. 78-79, paragraph 255).

VI. Grounds of Objection/Rejection to be Reviewed on Appeal

A. The rejection of claim 36 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 3,840,017 to Violante.

B. The rejection of claims 31 and 38-39 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 3,840,017 to Violante in view of U.S. Patent 5,681,333 to Burkhart et al.

C. The rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 3,840,017 to Violante in view of U.S. Patent 5,681,333 to Burkhart et al. and in further view of U.S. Patent 5,330,488 to Goldrath.

VII. Argument

A. Rejection under 35 U.S.C. 102(b) to Violante

Claim 36

Claim 36 has been concurrently amended to include the subject matter of now canceled claim 23. Claim 36 stands rejected under 35 U.S.C.102(b) as being anticipated by Violante. Violante does not disclose the apparatus recited in claim 36, because Violante does not disclose a suture passer comprising a cannula "...wherein at least a portion of the distal end of said cannula is configured to drive a suture against tissue without severing the suture." This feature is very clearly shown in Figures 42 and 43, and is described in the accompanying text of paragraph 222, which reads "[t]he cannula is preferably blunted or rounded off at 274 (see FIGS. 42 and 43) so as to minimize the possibility of damaging a suture during a tissue piercing operation, as will hereinafter be discussed in further detail." Paragraph 244 provides additional description of the blunt heel 274 and the overall shape of one embodiment of Applicant's cannula, with reference to Fig. 67.

Paragraph 228 describes the process of inserting suture through tissue: "[t]he pointed distal end of the suture passer's cannula 200 is then driven into and through the piece of tissue 500 (see FIG. 51). Paragraph 228 then describes how the blunt heal 274 help protect the suture during insertion: "[a]s this occurs, the suture extending out of the

cannula's sharp distal tip will be forced against the blunt heel 274 (see FIG. 43) of the cannula. The cannula's blunt heel 274 will support the suture during tissue penetration and prevent the cannula from cutting or otherwise damaging the suture as the suture is carried through the tissue." Clearly, the blunt heel 274 is a feature entirely different from and independent of the beveled shape of the cannula tip. Indeed, in the absence of the blunt heel 274, the interior surface of the trailing end of the bevel would have a very sharp acute angle due to the presence of the bevel. Such a sharp surface could easily sever suture during insertion, particularly where the suture will tend to be drawn against the sharp surface as it is pulled into the body.

In contrast, Violante states "that the surgical needle has a beveled and sharpened tip which assists in penetration of the skin, muscle and other tissue and at the same time presents a sharpened edge which the surgeon can employ in cutting of the suture material." (Violante col. 2, lines 27-32, Fig. 1). Nowhere does Violante disclose or suggest that a portion of the needle tip have a blunt heel, or disclose or suggest the modification of the sharpened tip 42 to facilitate driving the cannula into tissue without severing the suture as claimed by Applicant. Note that the sharpened tip 42 of the needle 20 of Violante possesses a beveled shape, as shown in Figures 1, 2, and 3. This beveled shape is also present in the alternative embodiments of the remaining figures. As described above, the bevel causes the interior surface of the trailing end of the bevel to be sharply acute. Thus, there is a distinct danger that a suture inserted through the use of the device of Violante will be severed during insertion. Violante discloses no contouring of this sharp surface to mitigate this danger.

B. Rejection under 35 U.S.C. 103(a) to Violante in view of Burkhart et al.

Claim 38

Claim 38 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Violante in view of Burkhart et al. Applicant asserts that claim 38 is not unpatentable over Violante in view of Burkhart et al., because (1) it is not clear that Violante can be combined with Burkhart, and (2) even if they could somehow be combined, there is no teaching or suggestion that would motivate a person of skill in the art to make the combination.

First of all, it is not clear that Burkhart and Violante are combinable. The flexible wire loop 66 of Burkhart has a flexible rod 68 that appears to be sized to require a larger cannula, such as the tube 52 of Figures 6 and 7. By contrast, the needle 20 of Figures 1-3 of Violante appears to be so narrow as to accommodate only a suture. Furthermore, the wire loop 66 has a handle 72 that appears to provide a significant mass on the proximal end of the wire loop 66. It also appears that the wire loop 66 is long enough that the handle 72 would protrude from the proximal end of the surgical instrument 10 of Violante, where the weight of the handle 72 would, depending on the length and stiffness of the flexible rod 68, tend to withdraw the wire loop 66 from the needle 20 or urge it further into the skin. This could be not only inconvenient for the surgeon, who may find that the wire loop 66 slips one way or another unexpectedly if constant thumb pressure is not maintained on the exposed portion of the flexible rod, but also dangerous for the patient because the wire loop 66 could be withdrawn to tighten suture prematurely, or could extend unexpectedly to damage internal body tissues.

In response to the argument that the dimensions and/or other features of the wire loop 66 could be altered to adapt it to combination with Violante, Applicants respectfully assert that such adaptation would be inventive, and suggesting such adaptation is using hindsight to apply Applicant's inventive work against him. Further, the mere fact that the wire loop 66 of Burkhart would have to be significantly altered to enable it to function with Violante shows that the combination would not be obvious to one of skill in the art. If prior art can be modified and then combined to defeat patentability, what inventions, then, would truly be patentable?

Applicants wish to bring the attention of the Board of Appeals to the U.S. Supreme Court's recent ruling in *KSR International Co. v. Teleflex Inc. et al.,* (Slip Opinion No. 04-1350). In *KSR*, the Supreme Court objected to the rigidity with which obviousness tests have been applied in the past. However, the Court still requires reasoning to back up the combination of prior art components in an obviousness rejection:

> [A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known.

KSR, p. 15. The Court reaffirmed that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, p. 14, citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006).

In the instant case, the only reasoning given by the Examiner to justify the combination of Violante and Burkhart is that "[s]uch an assembly would allow the advancement (and retrieval) of suture and suture loops (without breakage) in the small confines of Violante's passer assembly and surgical spaces as in a subacromial space." *Office Action*, Para. 5. Citing a benefit to the combination does not satisfy the requirement for providing a "rational underpinning" to support the obviousness conclusion. If such a citation were sufficient, virtually all inventions would be useful because "claimed discoveries almost necessarily will be combinations of what, in some sense, is already known" (previously quoted from *KSR*) and any invention that satisfies the utility requirement of 35 U.S.C. §101 (*i.e.*, any useful invention) would, by necessity, provide some benefit. Clearly, this is not how the Court intended for the obviousness test to be applied.

Even if it could be proved that modifying the wire loop 66 of Burkhart to adapt it for combination with Violante is an obviousness step, the Examiner still has not provided sufficient "rational underpinning" to justify the combination. Citing a benefit of the combination is not sufficient. Applicants respectfully assert that there is no such rational underpinning because the suture passer of claim 38 is truly inventive and represents a response to a need that simply was not addressed by the prior art, i.e., the need for a passer and puller assembly that can be operated with a single hand.

Claim 39

Claim 39 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Violante in view of Burkhart et al. Applicant asserts that claim 39 is not unpatentable for the same reasons set forth above for claim 38. In addition, claim 39 more specifically recites the interaction of the suture passer and puller assembly by stating that "the planar surface is adapted to support . . . said puller assembly shaft extending through said handle, such that the . . . puller assembly shaft [is] manually engageable by an operator for moving . . . said puller assembly shaft selectively in the direction of the nose portion and the cannula, and in the direction of the body proximal end portion." The Examiner again has not spelled out how this interaction would be obvious to one of skill in the art, beyond citing the benefit of Applicant's inventive work.

Claim 31

Claim 31 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Violante in view of Burkhart et al. Applicant asserts that claim 31 is not unpatentable, for the same reasons set forth above for claims 38 and 39. The Examiner again has not spelled out how the subject matter of the claim would be obvious to one of skill in the art, beyond citing the benefit of Applicant's inventive work.

C. Rejection under 35 U.S.C. 103(a) to Violante in view of Burkhart et al. and in further view of Goldrath

Claim 32

Claim 32 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Violante in view of Burkhart et al and in further view of Goldrath. Applicant asserts that claim 32 is not unpatentable, for arguments set forth above for claims 38 and 39

regarding the combination of Violante and Burkhart et al. In addition, there is no suggestion to combine the teachings of Goldrath with those of Violante and Burkhart et al. Violante does not suggest the use of a hook retriever or any kind of suture retriever in conjunction with the surgical instrument 10, and Burkhart et al. does not suggest the use of a hook retriever in conjunction with suture passer 50, or any other suture passer. Goldrath does not suggest the use of a hook retriever with an apparatus like the surgical instrument 10 of Violante. Furthermore, using a "hook retriever" as recited by claim 32 in combination with a suture passer presents unique challenges that are not addressed by Goldrath. Perhaps the largest challenge is that of how to pull the hook through the cannula without catching the curve of the hook on the outer wall of the cannula tip. This challenge is addressed by Applicant's disclosure, Figures 80-82, and the accompanying description at paragraphs 258-260. By contrast, the brief snippet of text from Goldrath cited by the Examiner (column 5, lines 42-48) does not remotely enable the use of a hook retriever with a cannula. Accordingly, the cited combination does not render claim 32 obvious because it is does not present an enabling disclosure of the subject matter recited by the claim. Additionally, the Examiner again has not spelled out how the subject matter of the claim would be obvious to one of skill in the art, beyond citing the benefit of Applicant's inventive work.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellants seek the Board's concurrence at this time.

Dated this 29th day of August, 2007.

Respectfully submitted,

/David Meibos/

David W. Meibos
Attorney for Applicants
Registration No. 45,885

MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321
Telephone: (435)774-1504
Facsimile: (435)753-7698

APPENDIX A

CLAIMS ON APPEAL

1.-30. (Cancelled)

31. The apparatus of claim 39, wherein the puller assembly is a loop retriever;

the planar surface permitting the loop retriever shaft to be articulated between a retracted position wherein said loop retriever is retained in said cannula, and an advanced position wherein said loop retriever is connectable to the suture.

32. The apparatus of claim 39, wherein the puller assembly is a hook retriever;

the planar surface permitting the hook retriever shaft to be articulated between a retracted position wherein said hook retriever is retained in said cannula, and an advanced position wherein said hook retriever is connectable to the suture.

33.-35. (Cancelled)

36. A surgical apparatus for delivering and retrieving suture, the apparatus comprising:

a cannula having a distal end, a proximal end, and a lumen extending therebetween; and

a handle having a distal end, a proximal end, a passageway extending through at least a portion of said handle, and an exposed surface disposed between the passageway and the distal end of said handle;

wherein the proximal end of said cannula is attached to said handle, with the lumen of said cannula being in communication with the exposed surface of said handle;

wherein the exposed surface is adapted to support a suture extending through said handle such that the suture is manually engageable by an operator for freely moving the suture selectively in the direction of the handle distal end and in the direction of the handle proximal end;

wherein said passageway is provided with an opening at the handle proximal end, and wherein the opening is positioned to permit the suture to be fed into the opening along a pathway parallel to the lumen;

wherein at least a portion of the distal end of said cannula is configured to drive a suture against tissue without severing the suture.

37. (Cancelled)

38. A surgical apparatus for delivering and retrieving suture, the apparatus comprising:

a passer assembly and a puller assembly;

said passer assembly comprising:

a handle and a cannula;

said handle comprising an elongated body having (i) a passageway extending distally from a suture entryway at a proximal end portion of said body, (ii) a recess in said body defining a planar surface generally extending along an axis of the passageway and disposed proximate a distal end of said body, and (iii) a nose portion extending distally of said recess and defining a bore in communication with the passageway and the planar surface; and

said cannula comprising an elongated tubular member defining a lumen, a proximal end of said cannula being adjacent to and in communication with said nose portion of said body, the lumen being in alignment with the bore of the nose portion; and

said puller assembly comprising:

a suture engager movable through the nose portion bore and through the cannula lumen, distally to connect to a suture and proximally to withdraw said suture engager and the connected suture.

39. The surgical apparatus in accordance with claim 38 wherein the planar surface is adapted to support a selected one of a suture extending through said handle and said puller assembly shaft extending through said handle, such that the suture and said puller assembly shaft are each manually engageable by an operator for moving the suture and said puller assembly shaft selectively in the direction of the nose portion and the cannula, and in the direction of the body proximal end portion for rearward movement of the puller assembly and suture out the axially disposed passageway at the proximal end of the body.

40.-41. (Cancelled)

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.